



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0801]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Export Notification and Recordkeeping Requirements

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under Review - Open for Public Comments” or by using the search function. The OMB control number for this information collection is 0910-0482. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 240-994-7399, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Export Notification and Recordkeeping Requirements

Sections 801 and 802 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 381 and 382) charge the Secretary of Health and Human Services, through FDA, with the responsibility of helping to ensure that exports of unapproved new drugs, biologics, devices, animal drugs, food, cosmetics, and tobacco products that are not to be sold in the United States meet the requirements of the country to which the product is to be exported. The respondents to this information collection are exporters who have notified FDA of their intent to export unapproved products that may not be sold or offered for sale in domestic commerce in the United States as allowed under section 801(e) of the FD&C Act. In general, the notification identifies the product being exported (e.g., name, description, and in some cases, country of destination) and specifies where the notifications were sent. These notifications are sent only for an initial export. Subsequent exports of the same product to the same destination or to certain countries identified in section 802(b) of the FD&C Act would not result in a notification to FDA.

Respondents to the information collection are exporters of products that may not be sold in the United States and are regulated by FDA’s Center for Drug Evaluation and Research (CDER); Center for Biologics Evaluation and Research (CBER); Center for Devices and Radiological Health (CDRH); Center for Veterinary Medicine (CVM); Center for Food Safety and Applied Nutrition (CFSAN); and Center for Tobacco Products. Respondents to this collection of information maintain records demonstrating their compliance with the requirements in 21 CFR 1.101.

In the *Federal Register* of January 25, 2022 (87 FR 3811), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
1.101(d) (CBER)	4	35	140	15	2,100

1.101(d) (CDER)	3	57	171	15	2,565
1.101(d) (CDRH)	22	4	88	15	1,320
Total					5,985

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

Table 2.--Estimated Annual Recordkeeping Burden¹

21 CFR Section	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
1.101(b), (c), and (e) (CBER, CDER, CDRH, CFSA, and CVM)	181	4.12	746	22	16,412
1.101(b) Office of International Programs only	1	65	65	22	1,430
1.101(b) (currently regulated Tobacco Products)	322	3	966	22	21,252
Total					39,094

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of Agency data, we decreased our estimate by 24,251 burden hours.

This decrease reflects an overall downward trend in the number of export certification requests across programs and commodities. The estimate for tobacco products remains steady.

Dated: April 19, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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